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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,103	03/10/2006	Ian Wilson	PZ02101	1240
36335 7590 07/28/2010 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231				
EXAMINER				
PERREIRA, MELISSA JEAN				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/28/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,103

Applicant(s)

WILSON ET AL.

Examiner

MELISSA PERREIRA

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 11, 12, 14 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/10 has been entered.

Claims and Previous Objections/Rejections Status

2. Claims 1,6,11,12,14 and 21-26 are pending in the application. Claims 11,12 and 14 are withdrawn from consideration. Claims 5,7-10,13,15-20 and 27-32 were canceled in the amendment filed 7/13/10.
3. The objection to claim 1 because of informalities is withdrawn.
4. The objection of claim 5 because of informalities is withdrawn.
5. The rejection of claims 1,5-8 and 17-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.
6. The rejection of claims 1,6 and 21-26 under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (WO02/067761) in view of Weinstock et al. (WO00/78145A1) is withdrawn.

Response to Arguments

7. Applicant's arguments with respect to claims 1,6, and 21-26 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to how at least one of the halogen substituents for R², R⁸ and R¹² is an imaging moiety as there is no radionuclide indicated in the instant claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

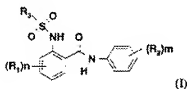
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstock et al. (WO00/78145A1).

12. Weinstock et al. (WO00/78145A1) discloses sulphonamidobenzamide macrophage scavenger receptor antagonists (MSRA) (below) for treating cardiovascular disease including but not limited to atherosclerosis, coronary artery disease, renal

disease, thrombosis, transient ischemia, etc. (abstract; p2, lines 26+; p3, lines 8+). R_1 and R_2 may be halo, hydrogen, alkyl, etc.; R_3 may be R_1 aryl, etc. wherein R_1 is halo (p3, lines 8-20) which anticipate the halogen substituents for R^2 , R^8 and R^{12} of the instant claims. The MSRAs may be formulated as pharmaceutical compositions and administered as tablets, liquid preparations, etc. (p11, lines 14+).



13.

14. The halogen substituents of the disclosure anticipate the halogen substituents for R^2 , R^8 and R^{12} of the instant claims and therefore are capable of the same functions and have the same properties, such as being an imaging moiety.

Claim Rejections - 35 USC § 103

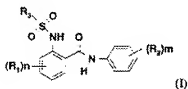
15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1,6 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al. (WO00/78145A1) in view of Edwards et al. (WO02/067761) and in further view of Choi et al. (US 5,820,873).

17. Weinstock et al. (WO00/78145A1) discloses sulphonamidobenzamide macrophage scavenger receptor antagonists (MSRA) (below) for treating cardiovascular disease including but not limited to atherosclerosis, coronary artery disease, renal

disease, thrombosis, transient ischemia, etc. (abstract; p2, lines 26+; p3, lines 8+). R_1 and R_2 may be halo, hydrogen, alkyl, etc.; R_3 may be R_1 aryl, etc. wherein R_1 is halo (p3, lines 8-20) which encompass the halogen substituents for R^2 , R^8 and R^{12} of the instant claims. The MSRAs may be formulated as pharmaceutical compositions and administered as tablets, liquid preparations, etc. (p11, lines 14+).



18.

19. The halogen substituents of the disclosure encompass the halogen substituents for R^2 , R^8 and R^{12} of the instant claims and therefore are capable of the same functions and have the same properties, such as being an imaging moiety.

20. Weinstock et al. does not teach that the at least one halo substituent (R_1 and R_2) is gamma-emitting or positron-emitting.

21. Edwards et al. (WO02/067761) discloses detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes for the diagnosis and monitoring of various cardiovascular diseases including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. (abstract; p37, lines 12-18). The complexes of the disclosure include $M-C_h-L_n-(BM)_n$ wherein M is a radionuclide (i.e. ^{99m}Tc , ^{111}In , ^{113m}In , etc.; C_h is a metal chelator (i.e. a N_4 ligand, N_2S_2 ligand); L_n is a linking group; and BM is a MSRA antagonist (p18-23; p26, lines 19+; p50, lines 6+; see claims). Edwards et al. also teaches of kits comprising the MSRAs of the disclosure (claims 38+).

22. Choi et al. (US 5,820,873) discloses that ^{99m}Tc and ^{125}I are analogous gamma-emitting radionuclides (column 14, lines 51-55).
23. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the MSRA antagonist of Weinstock et al. with a radionuclide for the diagnosis and monitoring of various cardiovascular diseases as Edwards et al. teaches that labeled MSRA complexes are used for diagnosing and monitoring cardiovascular diseases.
24. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute one gamma-emitting radionuclide, such as the ^{99m}Tc of Edward et al. for another analogous gamma-emitting radionuclide, such as ^{125}I of Choi et al. as Choi et al. teaches that ^{99m}Tc and ^{125}I are analogous gamma-emitting radionuclides and can be used interchangeably. Also, the simple substitution of one known, equivalent element for another yields predictable results, such as treating, diagnosing and monitoring cardiovascular diseases.
25. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to the formulate the detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes of the combined disclosures of Weinstock et al. and Edwards et al. as a pharmaceutical composition as Weinstock et al. teaches that MSRAs may be formulated as such.
26. The imaging moiety of the combined disclosure encompasses the imaging moiety of the instant claims and is capable of the same functions, such as being

detected externally in a non-invasive manner following administration of said labeled synthetic MSRA antagonist to the mammal body in vivo and has the same properties.

Conclusion

27. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618